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(54) BIOSTABLE TREATMENT DELIVERY SYSTEM

ABGABESYSTEM FÜR EINE BIOSTABILE BEHANDLUNGSFLÜSSIGKEIT
SYSTEME DE DIFFUSION BIOSTABLE POUR TRAITEMENT DENTAIRE

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(56) References cited:
**WO-A-92/06647 FR-A- 1 320 118
FR-A- 2 568 475 US-A- 3 527 219
US-A- 3 762 540 US-A- 3 896 808
US-A- 5 086 915**

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DescriptionIntroduction

This invention relates generally to treatment delivery systems and, more particularly, to a packaged system containing a treatment material and a separate treatment appliance which can be easily and readily combined in the packaged system prior to use.

Background of the Invention

In the treatment of teeth and/or gums, it is desirable that the treatment material be effectively delivered to the teeth or gums so that such material is in an activated form when placed in contact with the teeth or gums. A suitable appliance useful for such purpose is described, for example, in U.S. Patent No. 4,944,947 issued to M. H. Newman on July 31, 1990. As described therein, a horseshoe-shaped, foamed polymer dental appliance has an aqueous treatment solution distributed therein so that when the appliance is positioned over the teeth and gums of a patient, the treatment solution is readily applied thereto. The appliance need only be left in the patient's mouth for several minutes in order for an effective treatment to take place. Such treatment solution may be, for example, a fluoride solution, a bleach solution, or any other effective treatment solution.

Normally, the treatment solution is added to the foamed polymer during manufacture of the appliance and the wetted appliance is then shipped in an hermetically sealed pouch, or bag, for subsequent opening and removal of the appliance for use on a patient. Alternatively, a dry vacuum-formed dental impression tray appliance can be shipped in one package or container and the treatment solution shipped in a suitable vial or other container, which is separate therefrom. A dentist, or dental hygienist, for example, then must open both containers and apply the treatment solution to the dry foam polymer appliance before applying it to the patient.

Neither of the above techniques is satisfactory. In the first approach, the treatment solution may be physically squeezed from the foam polymer appliance and the drug may degrade due to oxidation. The foam polymer appliance then contains a reduced amount thereof and the treatment effectiveness is reduced. In the second approach, the handling of both the appliance and the solution may contaminate them, and also is inconvenient and untidy. Furthermore, the application of solution to the appliance is often inefficiently performed so that its treatment effectiveness is also reduced.

FR-A-1320118 of Bernadeau discloses a plug of absorbent material enclosing a capsule containing a dose of a liquid with which the absorbent material becomes impregnated when the capsule is opened. The liquid can vary depending on the intended use of the plug; for example if the liquid is an antiseptic the plug can be used to treat minor wounds.

It is desirable to devise a technique for handling a foam polymer appliance and a treatment solution in an antiseptic, easy-to-use, and efficient manner which assures a uniform distribution of solution throughout the foam polymer material so that the treatment effectiveness is maximised.

Accordingly the present invention provides a treatment delivery system in accordance with the precharacterising portion of claim 1 wherein:

10 the outer container is hermetically sealed and flexible,
 the inner container occupies only a specified region of the outer container,
 15 means are provided on said outer container for indicating the position of said inner container within said outer container,
 the dry foam element is located separate from the inner container and loosely placed within the outer container and when pressure is applied to the outer container said indicated means, the inner container bursts and said treatment solution comes into contact with said dry foam element so as to wet said foam element with the treatment solution, whereby
 20 the wetted foam element is available for delivery of said treatment solution.

The treatment solution inner pouch is made of a material which can be readily burst when pressure is applied thereto so that, when the appliance is ready to be used, the user merely applies pressure to the outer surface of the outer container at the region thereof where the treatment solution pouch is fixedly located. Such pressure bursts the treatment solution inner pouch and causes the treatment solution to be released within the hermetically sealed outer container. The user can then manipulate the outer container so that the treatment solution comes into contact with the dry foam appliance, the dry foam appliance is preferably a dental appliance.
 30
 35
 40 The treatment solution becomes readily absorbed into the foam polymer material and thereupon becomes effectively distributed throughout the wetted appliance. The user then opens the outer container so as to make the then wetted foam polymer appliance available, the wetted foam appliance is preferably applied to a patient's teeth and gums.

Description of the Invention:

50 **Fig. 1** shows a view of the exterior front surface of an overall container used in an embodiment of the invention;
Fig. 2 shows an exterior side view of the container depicted in **Fig. 1**;
Fig. 3 shows a view of a portion of the exterior front surface of the container depicted in **Fig. 1**; and
Fig. 4 shows a view in section of the portion of the container depicted in **Fig. 3**.

As can be seen in Fig.1, an outer container 10, which in the particular embodiment being described is made of a suitable plastic material, such as an aluminum laminate material on the outer surface of a polyester film base having a polyethylene layer on the inner surface thereof, for example, is hermetically sealed around its four edges as shown. A foam polymer appliance 11, (shown by dashed lines) such as one of the type described in the aforementioned U.S. Patent of M. Newman, is relatively loosely positioned within the interior of container 10. A treatment solution inner pouch 12 (shown by dashed lines), which is relatively smaller than container 10, is relative fixedly positioned at one corner of container 10 and has an edge 14 thereof positioned and sealed within the hermetic seal at edge 16 of outer container 10 so as to prevent undesired movement of inner pouch 12 within the container 10. Pouch 12 is positioned below a suitable exterior indicator 15, which is imprinted on the outer surface of container 10 in general registry with pouch 12. The indicator 15 may have a suitable legend, e.g., PRESS HERE, imprinted thereon, as shown.

Pouch 12 contains a treatment solution 27 which is to be distributed throughout foam polymer appliance 11. Such treatment solution may be a suitable fluoride solution, such as an aqueous solution of sodium fluoride, or may be a suitable bleaching, or whitening, solution, such as hydrogen peroxide. Pouch 12 is made of a thin film plastic material, such as a polyester, which is pre-scored along a pre-scored line 12A at the interior edge thereof opposite the edge which is sealed at edge 16 of outer container 10. The use of a thin film polyester material which is pre-scored allows for a relatively low burst strength so that when pressure is applied thereto, pouch 12 will readily burst at the pre-scored line 12A and make its contents readily available within the interior of container 10.

Thus, when a user, such as a dentist or dental hygienist, for example, desires to use the appliance on a patient, the user applies pressure firmly to the surface of container 10, which is placed on a surface, for example, at the indicator region 15 thereof, which action readily bursts pouch 12 so that the treatment solution 16 therein is released within the interior of container 10. The flexible outer container 10 can be manipulated by the user so as to make sure that the treatment solution comes into contact with the foam polymer appliance 11 where it is then absorbed and distributed throughout the foam polymer material.

The manipulation of container 10 after the pressure burst occurs, assures an effective spreading of the treatment solution within the container and into the foam material. Once the foam polymer appliance 11 is adequately wetted with the treatment solution, the container 10 can be opened by the user by tearing the container along a line between a pair of oppositely disposed notches 17 formed at opposite edges 18 and 19 of container 10. When the container is opened, the wetted ap-

pliance can be removed and inserted into a patient's mouth so that the treatment can take place, as discussed in the previously mentioned Newman U.S. Patent.

5 While the embodiment of the invention disclosed above represents a preferred embodiment thereof, modifications thereto may occur to those in the art within the scope of the invention. Hence, the invention is not to be construed as limited thereto, except as defined by 10 the appended claims.

Claims

15 1. A treatment delivery system comprising
 an outer container (10)
 an inner container (12) which is substantially
 smaller than the outer container (10) and is fix-
 edly positioned within said outer container (10),
 20 said inner container (12) containing a treatment
 solution and being readily burst upon the appli-
 cation of pressure thereto,
 a dry foam element (11) placed within said outer
 25 container
 characterised in that:
 the outer container (10) is hermetically sealed
 and flexible,
 the inner container (12) occupies only a speci-
 fied region of the outer container (10),
 means (15) are provided on said outer contain-
 30 er (10) for indicating the position of said inner
 container (12) within said outer container (10),
 the dry foam element (11) is located separate
 from the inner container (12) and loosely placed
 within the outer container (10), and when the
 35 pressure is applied to the outer container (10)
 at said indicated means (15), the inner contain-
 er (12) bursts and said treatment solution (27)
 comes into contact with said dry foam element
 (11) so as to wet said foam element (11) with
 40 the treatment solution (27), whereby the wetted
 foam element (11) is available for delivery of
 the treatment solution (27).
 45
 2. A treatment delivery system in accordance with
 claim 1 wherein said flexible outer container (10) is
 made of polyester film base having an aluminium
 laminate on one surface thereof and a polyethylene
 layer on the opposite surface thereof.
 50
 3. A treatment delivery system in accordance with
 claim 1 wherein said inner container (12) is a flexible
 plastic container made of a thin film plastic material
 such that said inner container (12) can be readily
 burst when pressure is applied thereto.
 55

4. A treatment delivery system in accordance with claim 3 wherein said inner container (12) is made of polyester. 5

5. A treatment delivery system in accordance with any preceding claim wherein said inner container (12) is pre-scored along an edge thereof. 10

6. A treatment delivery system in accordance with any preceding claim wherein said indicating means (15) is a legend imprinted on said outer container (10) in substantial registry with the position of said inner container (12) within the outer container (10). 15

7. A treatment delivery system in accordance with any preceding claim wherein said dry foam element (11) is a dental appliance and said treatment solution (27) is dental treatment solution. 20

8. A treatment delivery system in accordance with claim 7 wherein said dental treatment solution is a fluoride solution. 25

9. A treatment delivery system in accordance with claim 7 wherein said dental treatment solution is a bleaching solution. 30

Patentansprüche

1. Abgabesystem zur Behandlung, das aufweist: 35

 einen äußeren Behälter (10),
 einen inneren Behälter (12), der beträchtlich kleiner als der äußere Behälter (10) und fest in dem äußeren Behälter (10) angeordnet ist, wobei der innere Behälter (12) eine Behandlungslösung enthält und durch Ausübung von Druck darauf leicht zerbrochen werden kann,
 ein Trockenschaumelement (11), das in dem äußeren Behälter (10) angeordnet ist, 40

 dadurch gekennzeichnet, daß

 der äußere Behälter (10) hermetisch verschlossen und flexibel ist,
 der innere Behälter (12) nur einen spezifierten Bereich des äußeren Behälters (10) einnimmt, Einrichtungen (15) zur Anzeige der Lage des inneren Behälters (12) in dem äußeren Behälter (10) auf dem äußeren Behälter (10) vorgesehen sind,
 das Trockenschaumelement (11) von dem inneren Behälter (12) separat angeordnet und sich lose angeordnet in dem äußeren Behälter (10) befindet und bei Ausübung des Druckes auf den äußeren Behälter (10) an der angegebenen Einrichtung (15) der innere Behälter (12) 45

 zerbricht und die Behandlungslösung (27) mit den Trockenschaumelement (11) in Kontakt tritt und das Schaumelement (11) mit der Behandlungslösung (27) benetzt, wodurch das benetzte Schaumelement (11) zur Abgabe der Behandlungslösung (27) verfügbar ist. 50

2. Abgabesystem zur Behandlung nach Anspruch 1, wobei der flexible äußere Behälter (10) aus einer Folie auf Polyesterbasis mit einem Aluminium-Laminat auf einer Oberfläche davon und einer Polyethylenschicht auf der gegenüberliegenden Oberfläche davon hergestellt ist. 55

3. Abgabesystem zur Behandlung nach Anspruch 1, wobei der innere Behälter (12) ein so aus einem DünnenschichtKunststoffmaterial hergestellter flexibler Kunststoffbehälter ist, das der innere Behälter (12) durch Ausübung von Druck darauf leicht zerbrochen werden kann. 60

4. Abgabesystem zur Behandlung nach Anspruch 3, wobei der innere Behälter (12) aus Polyester hergestellt ist. 65

5. Abgabesystem zur Behandlung nach einem der vorhergehenden Ansprüche, wobei der innere Behälter (12) entlang einer Kante davon vorgekerbt ist. 70

6. Abgabesystem zur Behandlung nach einem der vorhergehenden Ansprüche, wobei die Anzeigeeinrichtung (15) eine auf den äußeren Behälter (10) aufgedruckte Legende ist, die sich im wesentlichen mit der Lage des inneren Behälters (12) in dem äußeren Behälter (10) deckt. 75

7. Abgabesystem zur Behandlung nach einem der vorhergehenden Ansprüche, wobei das Trockenschaumelement (11) eine Zahnvorrichtung und die Behandlungslösung (27) eine Zahnbehandlungslösung ist. 80

8. Abgabesystem zur Behandlung nach Anspruch 7, wobei die Zahnbehandlungslösung eine Fluoridlösung ist. 85

9. Abgabesystem zur Behandlung nach Anspruch 7, wobei die Zahnbehandlungslösung eine Bleichlösung ist. 90

Revendications

55 1. Ensemble de délivrance de traitement comprenant :

 un récipient extérieur (10),

un récipient intérieur (12), qui est notamment plus petit que le récipient extérieur (10) et qui est positionné, fixe, à l'intérieur dudit récipient extérieur (10), ledit récipient intérieur (12) contenant une solution de traitement et éclatant aisément lorsqu'une pression est exercée sur lui,
 un élément en mousse sec (11) placé à l'intérieur dudit récipient extérieur,
 caractérisé en ce que :

le récipient extérieur (10) est hermétiquement clos et souple,
 le récipient intérieur (12) occupe seulement un 15
 région spécifiée du récipient extérieur (10),
 un moyen (15) est prévu sur ledit récipient extérieur (10) pour indiquer l'emplacement dudit récipient intérieur (12) à l'intérieur dudit récipient extérieur (10),
 l'élément en mousse sec (11) est placé en étant 20
 séparé dudit récipient intérieur (12) et avec jeu
 à l'intérieur du récipient extérieur (10), et, lorsqu'on exerce une pression sur le récipient extérieur (10) au niveau dudit moyen d'indication 25
 (15), le récipient intérieur (12) éclate et ladite solution de traitement (27) vient en contact avec ledit élément en mousse sec (11) de manière à mouiller ledit élément en mousse (11) avec la solution de traitement (27), d'où il résulte que l'élément en mousse mouillé (11) est utilisable pour délivrer ladite solution de traitement (27).

2. Ensemble de délivrance de traitement selon la revendication 1, dans lequel ledit récipient extérieur souple (10) est fait d'un film polyester de base sur une surface duquel est appliqué un stratifié d'aluminium et dont l'autre surface est recouverte d'une couche de polyéthylène. 35
3. Ensemble de délivrance de traitement selon la revendication 1, dans lequel ledit récipient intérieur (12) est un récipient en plastique souple fait d'un mince film de matière plastique de telle sorte que ledit récipient intérieur (12) peut aisément éclater lorsqu'une pression est exercée sur lui. 45
4. Ensemble de délivrance de traitement selon la revendication 3, dans lequel ledit récipient intérieur (12) est en polyester. 50
5. Ensemble de délivrance de traitement selon l'une des revendications précédentes, dans lequel ledit récipient intérieur (12) est préalablement strié le long d'un de ses bords. 55
6. Ensemble de délivrance de traitement selon l'une

des revendications précédentes, dans lequel ledit moyen d'indication (15) est une légende imprimée sur ledit récipient extérieur (10) pratiquement en correspondance avec la position dudit récipient intérieur (12) à l'intérieur du récipient extérieur (10). 5

7. Ensemble de délivrance de traitement selon l'une des revendications précédentes, dans lequel ledit élément en mousse sec (11) est un dispositif dentaire et ladite solution de traitement (27) est une solution de traitement dentaire. 10
8. Ensemble de délivrance de traitement selon la revendication 7, dans lequel ladite solution de traitement dentaire est une solution de fluorure. 15
9. Ensemble de délivrance de traitement selon la revendication 7, dans lequel ladite solution de traitement dentaire est une solution de blanchiment. 20

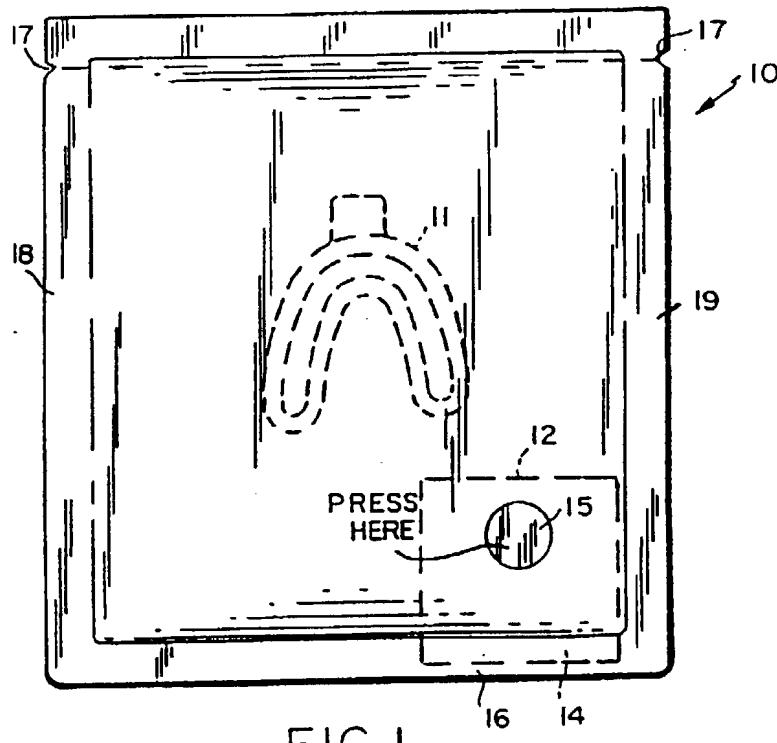


FIG. 1

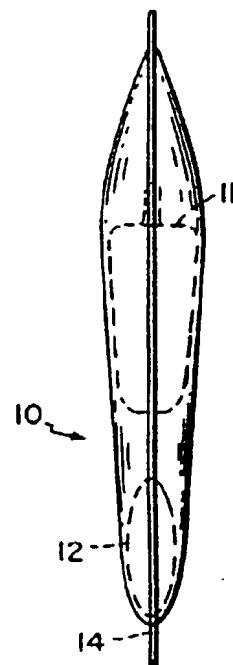


FIG. 2

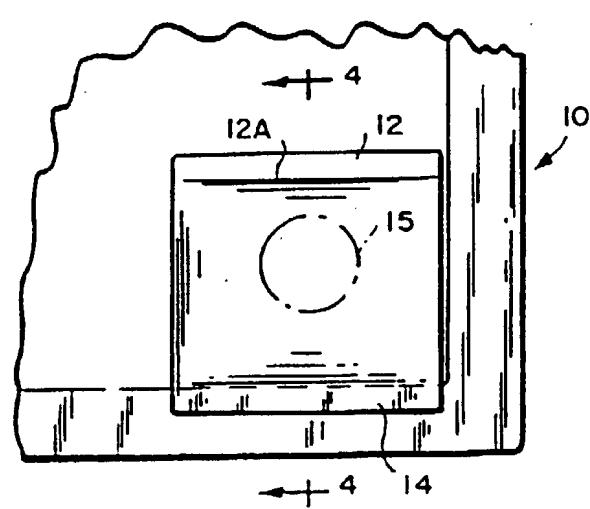


FIG. 3

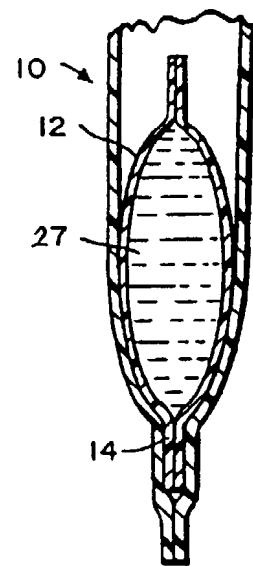


FIG. 4